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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,525	08/29/2005	Barry Sinclair Brewster	ISA-032.01	2520

63767 7590 10/27/2010
FOLEY HOAG, LLP (w/ISA)
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BOSTON, MA 02210-2600

EXAMINER

SIEFKE, SAMUEL P

ART UNIT	PAPER NUMBER
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1772

NOTIFICATION DATE	DELIVERY MODE
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10/27/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patent@foleyhoag.com

Office Action Summary	Application No.	Applicant(s)	
	10/519,525	BREWSTER ET AL.	
	Examiner	Art Unit	
	SAM P. SIEFKE	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,30 and 31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,5,30 and 31 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 5-30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jerome et al. (USPN 6,855,561).

Jerome teaches an assay device for detecting an analyte in a liquid sample, the assay device comprising:

a casing, the casing comprising at least one window (52);

a labeling region (34), the labeling region comprising a labeled binding agent (col. 16, lines 15-19); and

a nitrocellulose strip (18, example 1) located within the casing, the nitrocellulose strip being substantially opaque in a dry state and being translucent when contacted by the liquid sample (col. 4, lines 44-50), the nitrocellulose strip comprising:

(i) an analyte detection region (40) comprising an immobilized binding agent which binds the analyte, the analyte detection region located downstream of the labeling region (fig 1, ref. 40), wherein the analyte detection region is visible through the at least one window (52);

(ii) a printed line (46) located underneath the nitrocellulose in the analyte detection region, wherein the printed line is on the side of the nitrocellulose strip that is not visible through the at least one window when the nitrocellulose strip is in a dry state; and

(iii) a control region (fig. 4, 56), the control region located downstream of the analyte detection region (40), wherein the control region is visible through the at least one window (52); the nitrocellulose strip comprising an upper surface, a lower surface, and a line printed or deposited on the under the lower surface of the nitrocellulose strip;

wherein in use, the liquid sample contacts and migrates along the nitrocellulose strip, and wherein the printed line is visible to a user through the at least one window when the nitrocellulose strip is translucent,

where the line is oriented parallel with the direction of flow of the liquid (fig. 1, 56), and create a positive sign (fig. 1).

Jerome does not teach the printed line located on the lower surface of the nitrocellulose strip.

Jerome teaches a printed line (56) located on a separate surface 14 so that when the surface 14, test strip 18 and top casing are placed together, the sample wets the

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test strip 18 and the printed line located underneath the test strip is visible thereby providing a user with an indication that the test strip has been wetted and the device is working correctly. It would have been obvious to one having an ordinary skill in the art at the time of the invention to modify Jerome to locate the printed line on the underside of the nitrocellulose test strip because there would be no change in functionality of the prior art if the line was arranged on the nitrocellulose strip. In re Japikse, 86 U.S.P.Q. 70.

Response to Arguments

Applicant's arguments with respect to claims 1, 5 and 30-31 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAM P. SIEFKE whose telephone number is (571)272-1262. The examiner can normally be reached on Monday, Wednesday, Thursday and Friday 8am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, InSuk Bullock can be reached on 571-272-5954. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SAM P SIEFKE/
Primary Examiner, Art Unit 1772